NAVAL SHIPBOARD NON-TACTICAL ADP PROGRAM (SNAP)

AUTOMATED MEDICAL SYSTEM (SAMS)

COMPUTER ASSISTED MEDICAL DIAGNOSIS (CAMD) MODULE

FUNCTIONAL DESCRIPTION

T. R. Bonifield

J. D. Felson

Report No. 92-23

NAVAL HEALTH RESEARCH CENTER
P.O. BOX 85122
SAN DIEGO, CALIFORNIA 92186-5122

NAVAL MEDICAL RESEARCH AND DEVELOPMENT COMMAND
BETHESDA, MARYLAND

NAVAL
SHIPBOARD NON-TACTICAL ADP PROGRAM (SNAP)
AUTOMATED MEDICAL SYSTEM (SAMS)
COMPUTER ASSISTED MEDICAL DIAGNOSIS (CAMD) MODULE
FUNCTIONAL DESCRIPTION

Working Draft
Version 3.1
30 May 1992

Prepared for
Naval Medical Research and Development Command
Naval Health Research Center

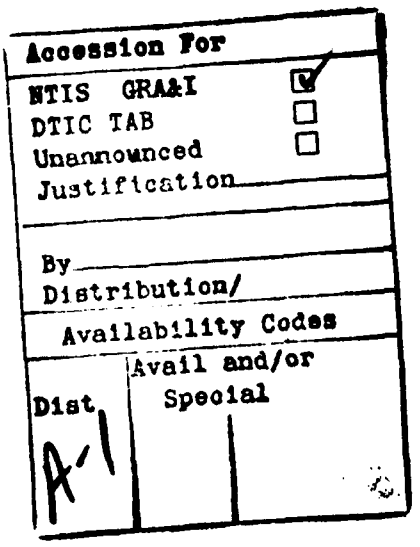
Prepared by
Public Health Service
Operational Medicine Informatics Laboratory

Report No. 92-23, supported by Naval Medical Research and Development Command, Bethesda, Maryland, Department of the Navy.

PREFACE

This document has been prepared on the basis of an inter-service Memorandum of Agreement (MOA) between the Naval Medical Research and Development Command (NMRDC), Naval Health Research Center (NHRC) in San Diego, California and the United States Public Health Service Operational Medicine Informatics Laboratory in Monterey, California. The Shipboard Non-tactical ADP Program (SNAP) Automated Medical System (SAMS) Computer Assisted Medical Diagnosis (CAMD) Module Functional Description (FD) was prepared according to DOD-STD-7935A, DOD Automated Information Systems (AIS) Documentation Standards, dated 31 October 1988. In particular, the CAMD FD meets the requirements for functional descriptions that are defined in Section 5.1 of DOD-STD-7935A.

The functional objective of the CAMD module is to provide computer-based medical decision and intelligence support for operational forces of the U.S. Government. Accordingly, the CAMD module will include not only diagnostic decision support capability, but also therapeutic and management plan formulation decision support as well as a medical library module/component. The library component should include high resolution visual and acoustical imagery.



Thomas R. Bonifield, Ph.D.
Research Scientist
United States Public Health Service

James D. Felson, M.D.
Medical Director
United States Public Health Service

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

EXECUTIVE SUMMARY

The Computer Assisted Medical Diagnosis (CAMD) module is being developed to provide Independent Duty Corpsmen aboard submarines and other ships and duty stations without physicians with a computerized patient management and medical diagnosis capability. The CAMD module will meet the following requirements:

1. Provide corpsmen with guidance when diagnosing illness and injuries.
2. Supply the corpsman with quick medical reference for patient care, diagnosis, and treatment.
3. Reduce unnecessary medical evacuations, and promote combat readiness by reducing medical evacuations.
4. Relieve the corpsman of some routine administrative paperwork.
5. Provide corpsmen computer-aided medical diagnosis training.

The CAMD module will be integrated into the Shipboard Non-tactical ADP Program (SNAP) Automated Medical System (SAMS). The CAMD module will be implemented in the FoxPro Version 2.0 programming language and use the MS-DOS 3.3+ operating system. The CAMD module will be initialized on the SAMS system, with no

programming required. Periodic updates of the CAMD module will be accomplished by installing a floppy diskette that will overwrite existing files and/or create new files. Confidentiality of patient medical data will be protected in accordance with the Federal Privacy Act of 1974 and SECNAVINST 5239.2.

The CAMD module will provide an expert system shell, essentially an empty framework into which developers of knowledge bases and diagnostic algorithms can add medical information, search engines, inference engines, rules, examples, and training scenarios. The six major functions of the CAMD module are the following:

1. Diagnostic Support Function: Provide medical diagnosis assistance.
2. Therapeutic Plan Function: Support therapeutic plan development.
3. Medical Reference Library Function: Provide a comprehensive source of medical reference data.
4. Diagnostic Encounter Record Function: Create a computer-stored, patient diagnostic encounter record.
5. Continuing Medical Education Function: Provide an on-site, computer-based tutoring capability.
6. Knowledge Base Authoring Function: Create and edit resident knowledge bases.

The CAMD module will employ a variety of methods for generating diagnostic recommendations including the Bayesian Method, the Expert Rule Based Method, Other Statistical Methods (including discriminant analysis and both nonlinear and logistic regression analysis), and the Artificial Neural Network Method. In the initial implementation of the CAMD module, Bayesian algorithms will be used to provide a diagnostic recommendation for two disease areas: abdominal pain and chest pain. In the future, additional areas of diagnostic assistance will be included using either rule-based or Bayesian algorithms.

Three organizations will participate in the research, test, and evaluation of the CAMD module. The Naval Submarine Medical Research Laboratory (NSMRL) will develop and evaluate diagnostic algorithms and the electronic medical reference library. The Public Health Service Operational Medicine Informatics Laboratory (PHS OMIL) will be responsible for large scale collection of clinical case data, and verification and validation of clinical data for evaluating the performance of the diagnostic algorithms. The Naval Health Research Center (NHRC) will develop the CAMD shell and provide necessary resources to conduct user testing. As overseer of the CAMD module development, NHRC will coordinate the various CAMD research efforts so that the CAMD module can be readily moved from an R&DTE environment to SAMS.

The CAMD module will use flexible software and hardware design and architecture to accommodate changing system requirements and to permit future interface with other information systems. The CAMD module will be expanded and improved as technology develops and new capabilities and resources become available.

SECTION 1. GENERAL

1.1 Purpose of the Functional Description. This Functional Description (FD) for the Naval Computer Assisted Medical Diagnosis (CAMD) module is written to provide:

a. Requirements which will serve as a basis for mutual understanding between users and developers.

b. Information on performance requirements, preliminary design considerations, and user impacts.

c. Information on fixed and continuing costs.

d. A definition of the input accepted by the CAMD module.

e. A definition of the output provided by the CAMD module.

f. A basis for the development of system tests for the CAMD module.

1.2 Project References. Computer Assisted Medical Diagnosis (CAMD) will provide an automated medical consultation module that will help Independent Duty Corpsmen in isolated operational settings without physicians, such as small surface ships,

submarines, or isolated bases, arrive at the relative probability of possible differential diagnoses when presented with clinical problems. The CAMD module will also provide therapeutic plan formulation support for specific diagnoses or disorders. The CAMD module has been developed as a medical research effort. The CAMD project is focused on the medical module that can be used for the Shipboard Non-tactical ADP Programs (SNAP) Automated Medical System (SAMS) to fulfill the medical capability requirement of the SNAP Mission Element Needs Statement (MENS).

The following references are applicable to the history and development of the CAMD project:

Documented Navy Requirements:

a. CNO ltr ser 987/5239822 of 9 July 1979: Science and Technology Objectives.

b. Chief BUMED ltr ser 10408029 of 15 Apr 1981: Evaluation at sea of a computer-based system to aid medical decision-making aboard submarines.

c. COMSUBLANT ltr FF4-12:004, ser 2309 of 23 May 1981 to CNO (OP-983): Evaluation at sea of a computer-based system to aid medical decision-making aboard submarines; request for Fleet T&E support of.

d. NMRDC ltr ser 3910 to CNO (OP-983) of 9 Dec 1981: Fleet T&E support for computer-assisted medical diagnosis system, K863 endorsed Chief BUMED ser 11209020.

e. Tentative Operational Requirement (TOR) developed in the Topical: Review: Combat Medical Material Research and Development OUSDRE, during 20-21 Nov 1984 at the Naval Submarine Medical Research Laboratory (Submarine Computer-Based Patient Management Systems).

f. Tri-Service Medical Information System, Functional Description for Shipboard Non-tactical ADP Program (SNAP) Automated Medical System (SAMS), March 1986.

g. Medical Requirement (MR) No. 3d of 14 December 1987: Computer-Aided Diagnosis for Submarine Systems.

h. CNO ltr 3900 ser 093 (933D4)/007 of 5 Jan 1988: Biomedical Research, Development, Test and Evaluation (RDT&E) Requirements Review Board: Minutes of 18 Dec Meeting.

i. Melaragno, NMRDC ltr 3900 ser 04/000584 of 3 May 1991: Restruct Prog Mngmt CAD Program Give NHRC Medical Decisions Dept. oversight of program.

j. DD 1498, 63706N - M0095.005-6103, Medical management tools.

k. DD 1498, 63706N - M0095.005-5010, Submarine deployable computer based system for enhanced medical practice, performance, and quality.

Relevant Navy Technical References:

a. Caras, B.G., Southerland, D.G., & Fisherkeller, K.D. MEDIC - ABDOMINAL PAIN: A Decision Support Program for the Management of Acute Abdominal Pain - USER'S MANUAL (NSMRL Report 1146). Groton, CT: Naval Submarine Medical Research Laboratory, 1989.

b. Dunbar, J., & Gino, A. Neural Networks and Their Possible Use in Computer-Assisted Diagnosis (Report No. 89-42). San Diego, CA: Naval Health Research Center, 1989.

c. Pugh, W.M., & Ryman, D.H. Comparisons of Regression and Neural Network Solutions to Known Functions (Report No. 91-33). San Diego, CA: Naval Health Research Center, 1991.

d. Ryman, D.H. Computer Assisted Medical Diagnosis Problems, and Methods To Minimize Their Effects (Report No. 91-32). San Diego, CA: Naval Health Research Center, 1991.

Other Relevant Technical Sources:

a. Barnett, G.O. The Computer and Clinical Judgment, The New England Journal of Medicine, 307 (1982), 493-494.

b. Barnett, G.O., Cimino, J.J., Hupp, J.A., & Hoffer, E.P. DXplain: An Evolving Diagnostic Decision-Support System, JAMA, 258 (1987), 67-74.

c. Blois, M.S. Clinical Judgment and Computers, The New England Journal of Medicine, 303 (1980), 192-197.

d. Charniak, E. The Bayesian Basis of Common Sense Medical Diagnosis, Proceedings of the National Conference on AI (pp. 70-73). AAAI, 1983.

e. Dobbins, R.W. Computer Assisted Medical Diagnostic System for Medical Practice Support System, The Johns Hopkins University, Applied Physics Laboratory, 5 Dec 1990 (Revision 1.5).

f. Dobbins, R.W. Entity-Relationship Diagrams for Medical Practice Support System, The Johns Hopkins University, Applied Physics Laboratory, 7 Jan 1991 (Revision 1.2).

g. Eberhardt, R.C., & Dobbins, R.W. Neural Network Versus Bayesian Diagnosis of Appendicitis, Proceedings of the Eleventh Annual IEEE EMBS Conference (pp. 78-80). Philadelphia, PA: November 1990.

h. Eberhardt, R.C., & Dobbins, R.W. (Eds). Neural Network PC Tools: A Practical Guide. San Diego, CA: Academic Press, 1990.

i. Gino, A., Pugh, W.M., & Ryman, D.H. MUMPS Based Integration of Disparate Computer-Assisted Medical Diagnosis Modules, MUG Quarterly, 20 (1990), 68-74.

j. Ledley, R.S., & Lusted, L.B. Reasoning Foundation of Medical Diagnosis: Symbolic Logic, Probability, and Value Theory Aid in Understanding of How Physicians Reason, Science, 130 (1959), 9-22.

k. Miller, R.A., Masarie, F.E., & Myers, J.D. Quick Medical Reference (QMR) for Diagnostic Assistance, M.D. Computing, 3 (1986), 34-48.

l. Miller, R.A., Pople, H.E., & Myers, J.D. INTERNIST-1, An Experimental Computer-Based Diagnostic Consultant for General Internal Medicine, The New England Journal of Medicine, 307 (1982), 468-476.

m. Reggia, J.A., & Perricone, B.T. Answer Justification in Medical Decision Support Systems Based on Bayesian Classification, Comput. Biol. Med., 15:4 (1985), 161-167.

n. Robinson, K.D., Ryack, B.L., Moeller, G., Post, R., & Shroeder, R.W. A Computer-Based Diagnostic/Patient Management System for Isolated Environments, Methods of Information in Medicine, 22 (1983), 131-134.

o. Shortliffe, E.H. Computer-Based Medical Consultations: MYCIN. New York: Elsevier/North Holland, 1976.

p. Stetson, D.M., Eberhardt, R.C., Dobbins, R.W., Pugh, W.M., & Gino, A. Structured Specification of a Computer Assisted Medical Diagnostic System, Third Annual IEEE Computer-Based Medical Systems Symposium, Chapel Hill, North Carolina, June 1990.

q. Weiss, S.M., Kulikowski, C.A., Amarel, S., & Safir, A. A Model-Based Method for Computer-Aided Medical Decision Making, Artif. Intel., 11 (1978), 145-172.

Applicable Standards Documentation:

a. Federal Information Processing Standards Publication 41, Computer Security Guidelines for Implementing the Privacy Act of 1974, 30 May 1975.

b. NAVDAC Publication 24.1, Life Cycle Management - Navy Data Automation Management Practices and Procedures: Project Management, 9 Mar 1983.

c. NAVDAC Publication 24.2, Life Cycle Management - Navy Data Automtation Management Practices and Procedures: System Decisions, 9 Mar 1983.

d. DOD-STD-7935A, DOD Automated Information Systems (AIS) Documentation Standards, 31 Oct 1988.

1.3 Terms and Abbreviations.

1.3.1 Terms. The following terms are used in this Functional Description (FD).

Artificial Intelligence (AI): A field of computer science that deals with problem solving by computer systems modeled after human intelligence.

Artificial Neural Networks: Massively parallel computing paradigms that involve many simple processing elements used to derive output values from a set of inputs. Artificial Neural Networks were developed to emulate neuronal structure and function of the brain.

Bayesian Method: A method for computing the posterior probability of an event from information on the prior probability of the event and associated conditional probabilities using Bayes Theorem: $P(A|B) = [P(A)*P(B|A)]/P(B)$.

Conditional Probability: The probability of each possible attribute given an event has occurred. For example, each possible combination of signs and symptoms given that a specific disease has occurred.

Database Management (DBM): A management approach to database design consisting of deciding what has to be collected, stored, and processed by computer software.

Domain: A specific subject area such as diagnoses associated with chest pain. Expert systems are best used when they are applied to a very specific, circumscribed domain.

Expert Rule-Based Systems: Artificial Intelligence (AI) computer systems that consist of knowledge bases and inference

engines that typically rely on IF-THEN-ELSE type rule processing to suggest answers.

Expert System: A computer program that embodies knowledge of a particular domain in conjunction with inferencing mechanisms that enable these mechanisms to use this knowledge to advise, analyze, categorize, communicate, consult, design, diagnose, explain, explore, forecast, form concepts, identify, interpret, justify, learn, manage, monitor, plan, present, retrieve, schedule, test, and tutor.

Expert System Shell: A domain-independent software tool for building expert systems. Minimally, a shell includes an inference engine, some means of entering rules or examples, and some means of using the system in a consultation mode. Shells may also provide a variety of tools that can be used in maintaining and debugging the knowledge base, and for interfacing with external programs and data. An expert system shell provides an empty framework into which users must add rules and facts.

Hybrid System: A system that implements a combination of computational methods for arriving at a result. For example, Bayesian and neural network procedures may be combined to reach a suggested medical diagnosis.

Inference Engine: Computer programs that combine data from a knowledge base and a database according to specific algorithms in order to generate a result.

Integrated Database: A filing system for data elements that avoids redundancy in a database.

Knowledge Base Editor: A utility program used to define and store the methods to be followed in order to reach a diagnosis and to provide an interface to the database.

Knowledge Representation: A discipline in which representative elements of a knowledge base are extracted from books, articles, or other documents to produce an integrated information source for facilitating the design of a decision support system.

Massachusetts General Hospital Utility Multi-Programming System (MUMPS): A compact, high-level interpretive data management system designed initially for medical applications. It is particularly suited for interactive applications that require a large shared database and the rapid, efficient manipulation of textual data. MUMPS is an American National Standards Institute (ANSI) programming language used by the Department of Defense, the Department of Veterans Affairs, and many other organizations, institutions, and vendors worldwide.

Modular Software Architecture: Computer software design in which separate parts (modules) perform the different functions of the entire integrated software system.

Neural Networks: A computing system that can process information to automatically derive ('learn') solutions by modeling the processes of biological neural nets.

Posterior Probability: The probability of an event occurring given an initial set of conditions. For example, the probability that a particular disease is present given information on the prior probability of the disease and the conditional probability for the signs and symptoms.

Prior Probability: The expected occurrence rate of an event for a specific population. For example, the expected occurrence rate of a disease in Navy personnel.

Shell Systems: Computer software systems that allow the system behavior to be modified by manipulating data files.

Subjective, Objective, Assessment, Plan (SOAP): A standardized medical format that organizes patient information according to the following categories: Subjective, Objective, Assessment, and Plan.

1.3.2 Abbreviations. The following abbreviations are used in this Functional Description (FD).

ADP	Automated Data Processing
AI	Artificial Intelligence
ANSI	American National Standards Institute
AQCESS	Automated Quality of Care Evaluation Support System
BUMED	Bureau of Medicine and Surgery, U.S. Navy
CAMD	Computer Assisted Medical Diagnosis
CAMIS	Computer Assisted Medical Interactive-Video System
CHCS	Composite Health Care System
CNO	Chief of Naval Operations
CO	Commanding Officer
DBM	Database Management
DNBI	Disease Non-Battle Injury
DOD	Department of Defense
DSS	Decision Support System
FD	Functional Description
IDC	Independent Duty Corpsman
MEDEVAC	Medical Evacuation
MENS	Mission Element Needs Statement
NAVMASSO	Navy Management Systems Support Office, Chesapeake, VA
NHRC	Naval Health Research Center, San Diego, CA

NMRDC	Naval Medical Research and Development Command, Bethesda, MD
NSMRL	Naval Submarine Medical Research Laboratory, Groton, CT
PHS OMIL	Public Health Service Operational Medicine Informatics Laboratory, Monterey, CA
RAPS	Resource Analysis and Planning System
SAMS	SNAP Automated Medical System
SNAP	Shipboard Non-tactical ADP Program
SOAP	Subjective, Objective, Assessment, and Plan
SVE	System Version Editor
TOR	Tentative Operational Requirement
TR	Technical Report (Internal Institutional Publication)
VA	Department of Veterans Affairs

The following are names of existing CAMD systems:

CADUCEUS

DXplain

INTERNIST-1

INTERNIST-1/QMR

MYCIN

ONCOCIN

The following are names of Neural Network programs:

BATCHNET

CASENET

EXSYS is the name of a rule-based Artificial Intelligence program.

SECTION 2. SYSTEM SUMMARY

2.1 Background. The absence of physicians on U.S. Navy submarines, small surface ships, and in remote shore locations requires that medical services be provided by Independent Duty Corpsmen. Navy medical practitioners on independent duty must rely on what they remember and what they can find immediately available when they treat personnel in isolated locations. Independent Duty Corpsmen typically have less extensive training and experience than those on major hospital staffs. Telephone or radio communication is commonly severely restricted, reducing the value of consultation as an information source. Print libraries available are restricted on weight and size and frequently are outdated. Multimedia sources, now common in universities, are totally absent.

Navy Independent Duty Corpsmen aboard submarines are solely responsible for the medical care of crews. While deployed, they need a rapid, reliable source of medical information to face uncommon medical problems and other clinical situations with which they have had little or no experience. These corpsmen must decide whether to treat a seriously ill patient on board or recommend evacuation. Evacuation is expensive, often compromises the ship's mission, and may be physically dangerous for both the patient and evacuation personnel. A decision support system would provide the Independent Duty Corpsman with an expert second

opinion in making a medical decision that may require a patient to be evacuated. As a result, the U.S. Navy has initiated a program to provide corpsmen with the Computer Assisted Medical Diagnosis (CAMD) module.

The overall requirement of the program is to provide computerized medical patient management and diagnosis to Independent Duty Corpsmen aboard submarines and other ships and duty stations without physicians. The program should meet the following requirements:

a. Provide corpsmen with guidance when diagnosing illness and injuries.

b. Supply the corpsman with quick medical reference for patient care, diagnosis, and treatment.

c. Reduce unnecessary medical evacuations, and promote combat readiness by reducing medical evacuations (MEDEVACS).

d. Relieve the corpsman of some routine administrative paperwork.

e. Provide corpsmen computer-aided medical diagnosis training.

In the late 1950's, medical diagnostic decision making (Ledley, & Lustad, 1959) included the combination of symbolic logic and conditional probability methods in deriving symptom disease complexes. The development of computer systems such as CASENET (Weiss, Kulikowski, Amarel, & Safir, 1978), INTERNIST-1 (Miller, Pople, & Myers, 1982), CADUCEUS (Blois, 1980), and MYCIN and ONCOCIN (Shortliffe, 1976) for diagnosing diseases, managing treatments, and training medical personnel has progressed rapidly. With this progress, more comprehensive disease diagnostic systems such as DXplain (Barnett, Cimino, Hupp, & Hoffer, 1987) and INTERNIST-1/QMR (Miller, Masarie, & Myers, 1986) have evolved.

Beginning in the late 1970's, work to develop a CAMD capability for Navy Hospital Corpsmen was initiated at the Naval Submarine Medical Research Laboratory (NSMRL). This effort led to the development of diagnostic algorithms for chest pain, abdominal pain, dental problems, psychiatric disorders, and ocular problems (Stetson, Eberhardt, Dobbins, Pugh, & Gino, 1990). These algorithms were incorporated into a set of "Stand Alone" modules. Subsequently, the Naval Health Research Center (NHRC) and the Applied Physics Laboratory of The Johns Hopkins University each developed an expert system shell (Gino, Pugh, Ryman, 1990; Stetson, et al., 1990) to apply these diagnostic algorithms in an integrated fashion. This approach provided the user with a common interface for all types of diagnosis, allowed

input for one module to be applied to another, and provided a maintenance capability for adding and deleting knowledge used by a diagnostic module. In addition, the NHRC CAMD shell was designed to support neural network algorithms, such as those developed by The Johns Hopkins University Applied Physics Laboratory (Eberhardt, & Dobbins, 1990).

2.2 Objectives. The overall objective of CAMD is to develop and field an automated medical consultation module that will help medical practitioners in isolated environments, such as small surface ships, submarines, or isolated bases, arrive at a differential diagnosis and therapeutic plan for specific illnesses and injuries. Integration of the proposed CAMD module into SAMS would help medical practitioners decide whether an illness or injury warrants evacuation and what preliminary care can be given to the patient during preparation for evacuation.

Specific objectives of the CAMD module are the following:

To provide medical practitioners having minimal familiarity with computers rapid access to accurate medical information. Support for both diagnostic assistance and therapeutic care will be met with information from expert knowledge library sources, remote databases, and training materials.

To provide intelligently managed access to medical information so that what is presented to the user is highly relevant to the request and the clinical context (viz., user skills and referral opportunities).

To avoid unnecessary, hazardous, and disruptive medical evacuations.

To improve medical care to forces afloat by providing independent duty medical practitioners with some of the benefits of second opinions based on the extensive clinical experience contained in the diagnostic module knowledge bases.

To evaluate the utility and success of computer assisted medical diagnostic programs deployed at sea.

To gather clinical information and modify the diagnostic module's knowledge bases as necessary to ensure diagnostic accuracy for the patient population with which the module is used.

To periodically update the knowledge base so that it reflects both accepted medical treatment and procedures mandated by higher authorities.

2.3 Existing Methods and Procedures. While dealing with the exponentially growing mass of medical information is a task that all medical professionals face, Navy medical practitioners assigned to small surface ships, submarines, and remote duty stations face the burden of providing high quality medical care with few information resources. Restrictions on weight and size of libraries, restricted access to communications, and limited facilities for patient transportation force practitioners to obtain patient care information from memory and from what can be easily carried and compactly stored.

Independent Duty Corpsmen (IDC) receive specialized medical training prior to assignment, which includes an introduction to the current version of SAMS, a version that does not at present include the proposed CAMD module. As a consequence, when a patient presents with a particular constellation of signs and symptoms, the corpsman arrives at a diagnosis based on memory and school training. He makes this judgment without the benefit of automated medical diagnostic assistance. Given enough time, he may consult available medical references, and depending on whether or not the information is current, appropriate, or even easy to find, he may obtain the medical diagnostic assistance he needs. In serious or life-threatening situations, he may attempt to communicate by radio with a medical officer to obtain a medically informed second opinion. However, radio access may not be available when he needs this assistance and/or a supporting

medical officer may not be accessible when needed. As a result, the corpsman may request an unnecessary medical evacuation or fail to recognize an urgent need for a medical evacuation. Figure 1 depicts the existing resources that may be used by the corpsman in making a differential diagnosis that could lead to a medical evacuation.

2.4 Proposed Methods and Procedures. For the past year, NHRC has worked to integrate the patient functions of the NHRC CAMD shell with those of the Shipboard Non-tactical ADP Program (SNAP) Automated Medical System (SAMS), a system which currently is in use at over 500 Navy facilities. The CAMD shell database design was used as a prototype for this integration. Programming for the enhanced patient encounter module was incorporated into Version 7.0 of SAMS. This software uses a controlled vocabulary, and adds the following capabilities to SAMS: an ICD-9-CM diagnosis look-up table, an SF600 facsimile, a Medical Evacuation data entry form, an expanded patient encounter, and monthly morbidity reporting functions. Remaining functions of the CAMD shell to be integrated with SAMS are computer assisted diagnostic support, an electronic medical reference library, treatment recommendations, and training routines.

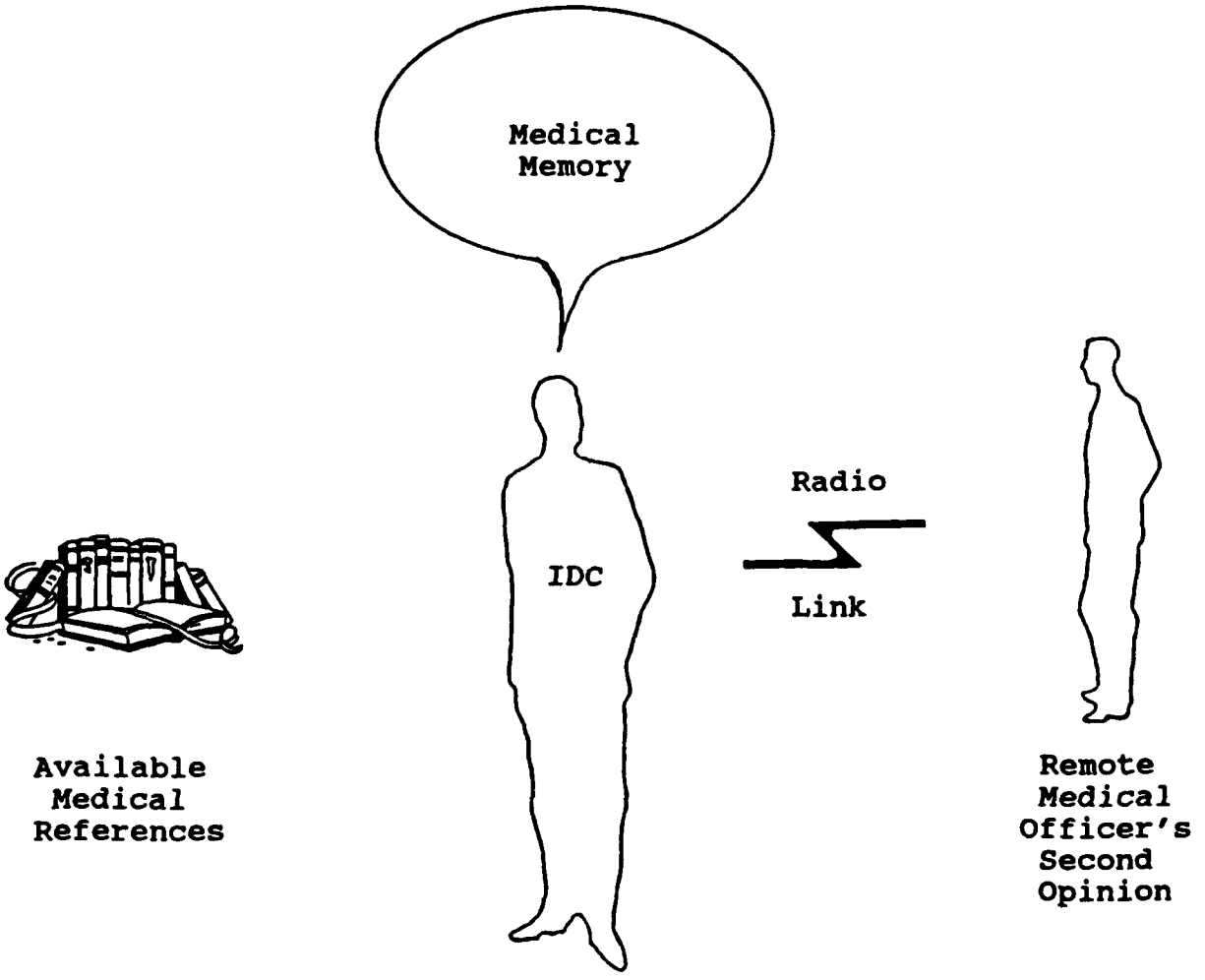


Figure 1. Existing Resources That May Be Used by the Independent Duty Corpsman in Making a Differential Diagnosis.

In May 1991, the Naval Medical Research and Development Command (NMRDC) assigned NHRC's Medical Information Systems and Operations Research Department responsibility for oversight and project management of the CAMD program. NSMRL was tasked with developing and evaluating the diagnostic algorithms for chest pain, abdominal pain, ocular problems, dental problems, trauma, and possibly gynecologic and psychiatric disorders as well as developing the electronic medical reference library. The Public Health Service Operational Medicine Informatics Laboratory (PHS OMIL) was made responsible for large scale data collection of chest pain, abdominal pain, and eye disease clinical cases and for verification and validation of the clinical data in these cases. These data will be used by NSMRL to test, evaluate, and compare diagnostic algorithms. NHRC will develop the CAMD shell into which the best performing diagnostic algorithms, medical reference material, and treatment information can be loaded. As overseer of the CAMD program, NHRC will coordinate the various CAMD research efforts so that the CAMD module can be readily moved from an R&DTE environment to SAMS. Organizations contributing to the implementation of the CAMD module are shown in Figure 2.

The CAMD module will provide enhancements to SAMS to help medical practitioners in isolated environments arrive at a differential diagnosis and a therapeutic plan to manage an injury or illness. A database management approach will be used to allow

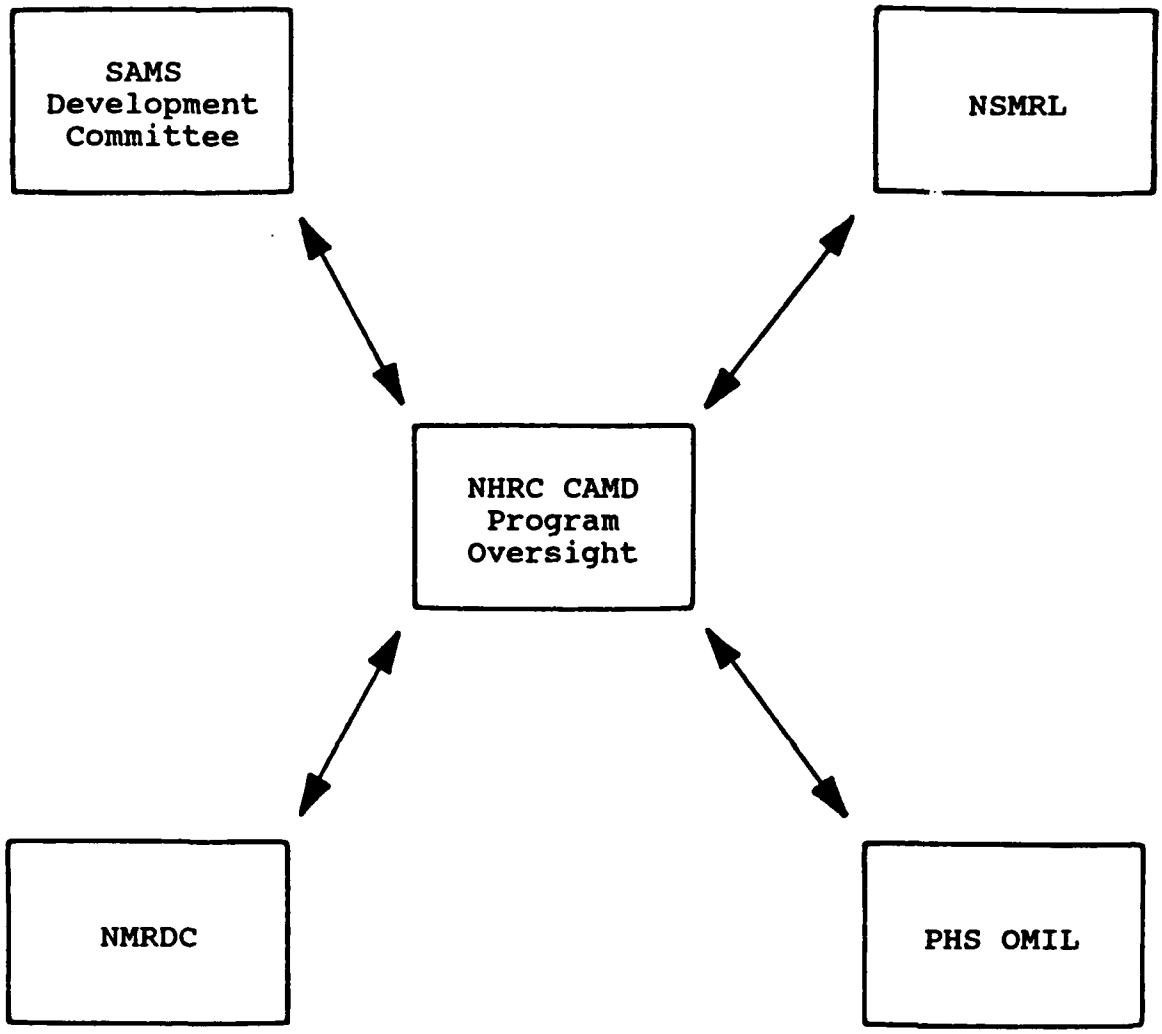


Figure 2. Organizations Contributing to the Implementation of the CAMD Module.

for transfer of patient data from SAMS to the CAMD module and return of a Diagnostic Encounter Record to SAMS.

The six proposed major functions of the CAMD module are the following:

a. Diagnostic Support Function: Provide medical diagnosis assistance using information from the medical practitioner and from patient data obtained during previous encounters. This function will provide diagnostic support. Computational techniques may include expert rules; statistical approaches including Bayesian techniques, multiple regression, and discriminant functions; and neural network methods. CAMD should disclose how a diagnosis was made.

b. Therapeutic Plan Function: Support therapeutic plan development. This capability will facilitate proper management of the patient after a diagnosis has been rendered. The function will take

into account resources available (e.g., available supplies and equipment) and the circumstances surrounding the event (e.g., ship location).

c. Medical Reference Library Function: Provide a comprehensive source of medical reference data. This capability should contain text, visual material, audio data, and BUMED-approved Navy instructions as appropriate. This function will be accomplished by a smart search engine capable of rapidly locating desired material.

d. Diagnostic Encounter Record Function: Create a computer-stored, patient diagnostic encounter record. This function will access patient demographic data such as sex and data of birth from SAMS, record the date/time stamped differential diagnosis made by the medical practitioner, and pass this diagnostic encounter record to SAMS.

e.	Continuing Medical Education Function:	Provide an on-site, computer-based tutoring capability. This function will provide for continuing medical education, including levels of training to match the expertise of the user.
f.	Knowledge Base Authoring Function:	Create and edit resident knowledge bases. This capability will allow knowledge data to be entered, edited, updated, and retrieved without the author being required to know the file structure. The module will be under total Life Cycle Configuration Management and diagnostic algorithms will be updated based on verified improved performance.

The CAMD module will create an integrated database constructed of data from the following sources:

- Patient demographic, medical, diagnostic, and treatment records resident in SAMS
- Input from the medical practitioner concerning a patient's presenting signs and symptoms

- Diagnostic algorithms and their associated knowledge bases
- A library of medical reference data
- Treatment plans appropriate to diseases and injuries

The proposed data flow among the Independent Duty Corpsman (IDC), the CAMD module, and SAMS is depicted in Figure 3.

The CAMD module may employ any of several methods to generate a diagnosis. The various diagnostic methods are the following:

a. **Bayesian Method** - A method for computing the posterior probability of an event from information on the prior probability of the event and associated conditional probabilities using Bayes Theorem:
$P(A|B) = [P(A)*P(B|A)]/P(B)$.

b. **Expert Rule Based Method** - An Artificial Intelligence (AI) computer system that consists of an inference engine and one or more knowledge bases. The inference engine examines known data, asks questions to obtain unknown data, and arrives at a probable solution according to a set of IF-THEN-ELSE rules in the knowledge base.

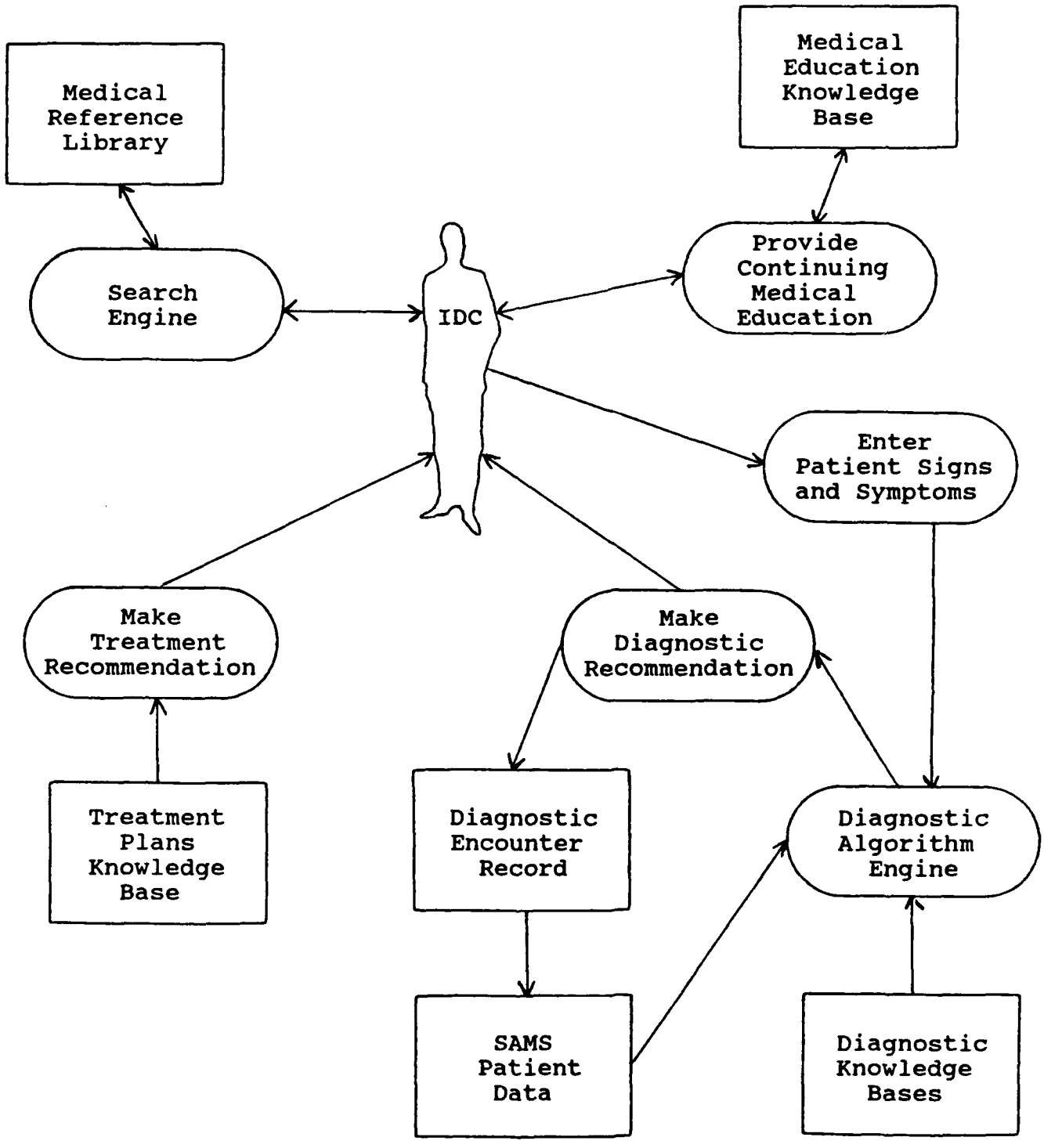


Figure 3. Proposed Data Flow Among the Independent Duty Corpsmen, the CAMD Module, and SAMS.

c. **Other Statistical Methods** - Candidate methods are discriminant analysis and both nonlinear and logistic regression analysis.

d. **Artificial Neural Network Method** - Massively parallel computing paradigms that involve many simple processing elements used to derive output values from a set of inputs. Artificial Neural Networks are inspired by neuronal structure and function of the brain.

2.4.1 Summary of Improvements. The proposed CAMD module will create a common patient care database that can be accessed and shared by different diagnostic methods. The interpretation of the method used in arriving at the suggested diagnosis will be clear to the user. In addition, the CAMD module will deliver appropriate medical knowledge from multiple sources.

The CAMD module will:

a. Improve diagnostic and therapeutic plan support for corpsmen.

b. Increase quality of care through diagnostic assistance and treatment guidelines.

c. Increase awareness of abnormal or exceptional conditions, information, and data through access to extensive and current medical information.

d. Provide computerized medical reporting of illness and injuries.

e. Reduce the need for external communications.

f. Avoid unnecessary, hazardous, and disruptive medical evacuations.

g. Regularly update the diagnostic module's knowledge bases.

h. Decrease training costs and time.

In addition, the CAMD module will:

a. Allow quick incorporation of new areas of disease.

b. Be easier to maintain and modify.

c. Support logical groupings of patient, diagnostic, treatment, and laboratory information for faster data entry and recall.

2.4.2 Summary of Impacts. Proposed enhancements will:

a. Increase diagnostic and therapeutic plan proficiency of medical practitioners.

b. Allow medical practitioners to respond more rapidly and effectively to illnesses and injuries.

c. Reduce unnecessary medical evacuations.

d. Increase accessiblity to medical information and diagnostic and therapeutic data.

e. Enhance the quality of information available to medical practitioners in isolated environments.

f. Make additional computer-aided training opportunities available to corpsmen.

g. Improve and maintain the health of Navy and Marine Corps personnel.

Only a minimum of computer literacy will be required of corpsmen who use the CAMD module since it will be interactive and menu driven. Extensive on-line help will be available as well as a user's manual and a reference card delineating the frequently used function keys. A by-product of this integrated module will be the development of electronic forms that are transferable without the filing, storage, and waste problems of hard copy. After the CAMD module has undergone both component and integration testing, it will be field tested. Upon acceptance, the module will be turned over to SAMS operational personnel who will be responsible for providing documentation and training materials.

2.4.2.1 User Organizational Impacts. No user organizational impacts are anticipated by integration of the CAMD module into the SAMS system.

2.4.2.2 User Operational Impacts. Navy medical practitioners will use the CAMD module as an integral part of daily medical operations in isolated environments. Ongoing use will result in a better determination of when to evacuate a patient.

2.4.2.3 User Development Impacts. No user development impacts are anticipated. Component and integration testing of the CAMD module will take place at NHRC. The module then will be integrated into the existing SAMS system for field testing. Once that the CAMD enhancements are reviewed and accepted by the SAMS working group, the NAVMASSO Quality Assurance group will review the integrated system to assure that the software is reliable and maintainable. Upon a successful reviewing by NAVMASSO, the software can be distributed to the active SAMS sites.

2.5 Assumptions and Constraints. The assumptions and constraints listed below pertain to the current SAMS software and hardware environment. If SAMS changes, the assumptions and constraints will also change.

2.5.1 Assumptions.

a. The CAMD module will be initialized on the SAMS system using floppy diskettes.

b. Resources will be available for CAMD module development, enhancement, maintenance, acquisition, and deployment.

c. The CAMD module will be expanded and improved as technology develops and new capabilities and resources become available.

d. Periodic updates of the CAMD module on the SAMS system will be accomplished by installing a floppy diskette.

e. The module will reduce administrative workload.

2.5.2 Constraints.

a. Reliable and accurate diagnostic methods depend on knowledge from experts and data verification and validation using large samples of cases. This information must be representative and adequate in terms of number of cases, and quantity and quality of data for the disease area.

b. The CAMD module software must be compatible with SAMS Version 7.0 software and the MS-DOS 3.3+ operating system.

c. The CAMD module software must operate on the same hardware as SAMS.

d. Integration of the CAMD module into SAMS should require a minimum of new software or hardware purchases.

e. Data files must comply with Privacy Act requirements, medical records confidentiality, and security considerations.

f. The CAMD module must be flexible enough to satisfy user needs for a variety of organizational structures, sizes, missions, and resources.

g. The CAMD module must avoid duplication of data files.

h. Input techniques should mirror existing medical records, standard forms, and administrative procedures. Input techniques must be efficient in terms of time, effort, and significance.

SECTION 3. DETAILED CHARACTERISTICS

The proposed CAMD module will develop automated medical consultation support capabilities that will assist isolated medical practitioners and enhance their diagnostic skills. The module will use multiple methods for making diagnostic predictions. The module will also provide on-line medical references and continuing education.

3.1 Specific Performance Requirements. The CAMD module will include:

a. An integrated patient and knowledge database.

b. A capability for disease and treatment descriptions and definitions to be easily entered and updated.

c. At least four major diagnostic techniques: Bayesian Method, Expert Rule Based Method, Other Statistical Methods, and Artificial Neural Network Method.

d. The capability for rapid incorporation of verified and validated improvements to existing diagnostic algorithms and the incorporation of new verified and validated diagnostic algorithms, rapid updating of

knowledge base files and related tables, and creation of new menu and screen items.

e. A database management approach for transferring patient data from SAMS to the CAMD module and returning a Diagnostic Encounter Record to SAMS.

f. The integration and use of properly formatted, textual data maintained in SAMS.

g. An interactive and menu-driven operation that requires only a minimum of computer literacy. Extensive on-line help will be available as well as a user's manual and a reference card delineating the frequently used function keys.

h. The ability to store patient demographic, medical, diagnostic, and treatment information in formats that can be used by the various diagnostic methods.

i. Access to relevant medical reference data.

j. The opportunity for continuing medical education.

k. The appropriate security and access control requirements.

l. A method that requires minimal key strokes to select a function.

m. Display of a message to acknowledge acceptance of data. Error messages include directions for recovery. The CAMD module will indicate that it is functioning if processing time is longer than 2 seconds.

n. Context-sensitive help screens and on-line tutorials.

o. Clear, comprehensive documentation consisting of a user manual, an operations guide, and instructions for installing new diskettes into SAMS.

The CAMD module must create and maintain patient demographic, medical, diagnostic, and treatment information. This information will be stored in formats that can be used by the various diagnostic methods and in multiple disease areas.

The CAMD module will request information in a clear and logical manner, specifically, in the Subjective, Objective, Assessment, Plan (SOAP) format. It will gather information in an order that can be specified, for example, past to current medical history, examination findings, and laboratory results. The interpretation of the method used by the module to generate the suggested diagnosis or therapeutic plan will be available to the

user. The interpretation will be available either in the form of medical literature citations for the significant disease indicators, a list of the rules triggered by the responses, or those significant signs and symptoms that led to a differential diagnosis.

3.1.1 Accuracy and Validity. The module must be accurate from both a medical and software standpoint, that is, the diagnostic algorithms must strive to suggest the same diagnoses as those considered correct by medical experts. Verified patient case data will be used to test the validity of the various diagnostic algorithms, and the best performing algorithm will be used for each disease area. As diagnostic algorithms are improved or new algorithms are developed and validated, they will be incorporated into the CAMD module. Electronic libraries for medical reference information and treatment planning will be kept current and as accurate as possible. Library contents will be updated as medical knowledge changes.

3.1.1.1 Proposed Diagnostic Algorithms. Proposed diagnostic algorithms will be submitted for validation in the designated format of each knowledge base. Documentation will be provided on the method used to develop and test the algorithms. Test data and an Independent Verification and Validation Plan will also be provided. Proposed algorithms will be reviewed by appropriate

medical functional authorities as designated by NMRDC. Approved diagnostic algorithms will be added to the CAMD module by loading the knowledge base provided. Test data will be used to exercise the algorithms before they are deployed as part of the CAMD module.

3.1.1.2 System Data. The CAMD module will validate data as they are entered interactively by the user or as they are received from other automated sources. Validation checks will prevent entry of incorrect or duplicate information. The module will check data for the following:

a. Redundancy. The user will be prevented from creating more than one registration for each patient or posting the same medical data more than once.

b. Integrity. A determination that the CAMD module has a viable database each time it is booted.

c. Input validity. A determination when data are entered that they meet anticipated values or lie within expected ranges.

d. Consistency of external data input. Portions of the CAMD module database come from existing data and external sources. The module will check data from each

source for consistency in specific fields such as patient name, sex, date of birth, and social security number.

3.1.2 Timing. The CAMD module will operate in an interactive environment and must provide current and accurate patient data that are easily entered and retrieved. Response time is defined as the time that the computer needs to respond and carry out a user request. Response time is usually measured from the moment that the user presses the Enter Key until the first character of the response is displayed on the screen. Response time requirements are defined below.

a. Interactive Response Time. Interactive processing occurs when a user communicates with computer software in a conversational manner. The computer's operations are monitored directly on a video display so that the user can catch and correct errors before the processing operation is completed. Interactive response time is measured from the moment that the user presses the Enter Key until the first response character displays on the screen. Interactive response time will be less than 1/4 second for interactive functions. This time does not apply to interface with external systems, generation of reports, extensive file updates, or

extensive database searches. The generation of a diagnosis, depending on the complexity of the diagnostic algorithm being computed or interpreted, may take 10-20 seconds. An upper limit of 20 seconds is acceptable.

b. On-Demand Response Time. On-demand processing is the request for hard copy output. On-demand processing includes requests for preprogrammed reports. The CAMD module will return access to the user within 5 seconds of the execution of the request while continuing compilation of the report.

The response time for on-demand output is measured from the time that the user transmits the request until the output is initiated or queued. The CAMD module will be available to the user for the next task within 5 seconds after the request. The output will begin printing or will be queued in less than 5 seconds.

c. On-line HELP Response Time. The response time for on-line help is measured from the time that the user transmits the request until the output is displayed on the user's screen. The response time for on-line help should be less than 2 seconds.

It should be noted that SAMS system response time depends on the internal clock speed of the computer hardware on which SAMS is running. When SAMS is moved to a faster hardware platform, system response times will decrease accordingly.

3.1.3 Capacity Limits. The CAMD module will consume 5 percent or less of SAMS total capacity.

3.2 Functional Area System Functions. The following paragraphs relate the major functions of the CAMD module to performance requirements, and amplify and describe the major functional processing steps by individual function. The six major functions of the CAMD module are the following:

a. Diagnostic Support Function: Provide medical diagnostic assistance. The CAMD module will include an integrated patient and knowledge base by utilizing a database managed approach. The Diagnostic Support Function will include the following subfunctions:

(1) Register a new patient.

(2) Request demographic and medical encounter data from SAMS for patients already registered in SAMS.

(3) Enter and edit a patient's presenting signs and symptoms.

(4) Request medical diagnostic assistance.

(5) Calculate or interpret diagnostic algorithms by one or more of the following techniques: Bayesian Method, Expert Rule Based Method, Other Statistical Methods, and Artificial Neural Network Method.

(6) Present calculated or interpreted differential diagnoses to the medical practitioner.

(7) Inform the medical practitioner about how a diagnosis was rendered.

b. Therapeutic Plan Function: Support therapeutic plan development. The Therapeutic Plan Function will include the following subfunctions:

(1) Request treatment planning appropriate to a particular diagnosis, taking into account the resources available to administer the treatment and the circumstances surrounding the patient encounter.

(2) Advise the medical practitioner of drug-to-drug interactions and any counter indications.

(3) Inform the medical practitioner of medical literature citations from which the therapeutic plan was extracted.

(4) Provide an easy way to enter, edit, and update treatment descriptions and definitions.

c. Medical Reference Library Function: Provide a comprehensive source of medical reference data. The Medical Reference Library Function will include the following subfunctions:

(1) Request a search for desired medical information by word, author, subject, or title.
(2) Display and highlight retrieval "hits."
(3) Print retrieved documents, or copy to file.
(4) Maintain and update the contents of the electronic medical reference library.

d. Diagnostic Encounter Record Function: Create a computer-stored, patient diagnostic encounter record. The Diagnostic Encounter Record Function will include the following subfunctions:

(1) Use a database management approach to allow for transfer of patient data from SAMS to the CAMD module and return of a Diagnostic Encounter Record to SAMS.
(2) Access pertinent patient demographic and medical data from SAMS in the SOAP format.

(3) Enter and edit a patient diagnostic encounter record.

(4) Store patient demographic, medical, diagnostic, and treatment information in formats that can be used by the various diagnostic methods and in multiple disease areas.

(5) Record the date/time stamped differential diagnosis selected by the medical practitioner.

(6) Pass the diagnostic encounter record to SAMS in the SOAP format.

e. Continuing Medical Education Function: Provide an on-site, computer based tutoring capability. The Continuing Medical Education Function will include the following subfunctions:

(1) Provide training scenarios for learning how to use the diagnostic and treatment planning support available in the CAMD module.

(2) Allow the medical practitioner to browse the electronic medical reference library to enhance his medical acumen.

f. Knowledge Base Authoring Function: Create and edit resident knowledge bases. The Knowledge Base Authoring Function will include the following subfunctions:

(1) Allow knowledge data to be entered, edited, and retrieved without the author being required to know the file structure.

(2) Provide for the rapid updating of knowledge base files and related tables.

(3) Allow for the rapid incorporation of verified and validated improvements to existing diagnostic algorithms.

(4) Allow for the rapid incorporation of new verified and validated diagnostic algorithms.

The CAMD module will potentially use at least four major diagnostic methods to manipulate the database:

a. **Bayesian Method** - A method for computing the posterior probability of an event from information on the prior probability of the event and associated conditional probabilities using Bayes Theorem:

$$P(A|B) = [P(A)*P(B|A)]/P(B).$$

In the case of medical diagnosis determination, the prior probability of the ith disease

$$P(d_i)$$

and the conditional probability of each possible combination of signs and symptoms

$$P(S|d_i)$$

are used to compute the posterior probability of the ith disease

$$P(d_i|S) = \frac{P(d_i)P(S|d_i)}{\sum_{j=1}^{n} P(d_j)P(S|d_j)}$$

where n is the number of different diseases in the problem area.

Finally, because it is assumed that the various features of S (e.g., the array of symptoms, S_k) are independent, $P(S|d_i)$ is computed as follows:

$$P(S|d_i) = \prod_{k=1}^{m} P(S_k|d_i)$$

where m is the number of signs and symptoms.

b. **Expert Rule Based Method** - An Artificial Intelligence (AI) computer system that consists of an inference engine and one or more knowledge bases that typically rely on IF-THEN-ELSE type rule processing to suggest answers. The rule based method will have the capability of performing both backward and forward chaining.

c. **Other Statistical Methods** - Nonlinear and logistic regression, and discriminant classification functions

will be supported. For each of these statistical methods, the CAMD module knowledge base editor will incorporate the following information, provided by the diagnostic algorithm developer, to calculate a predicted diagnosis:

(1) The classification weights for each disease sign and symptom.
(2) Any summation required for sign and symptom disease scales.
(3) Classification function constants.

d. **Artificial Neural Network Method** - Massively parallel computing paradigms that involve many simple processing elements used to derive output values from a set of inputs. The basic components of a Neural Network include the following:

(1) Architecture - The specification of the interconnections of nodes in a neural network, including topology, learning paradigms, and methods.
(2) Activation Function - The output of a processing element (node) expressed as a function of the input.

(3) Learning Rule - The method that is used to train the variable weights for each connection in the network. Sometimes it also involves changing other parameters, and even the topology of the network.

The CAMD module will be constructed as an integrated database from the following data sources:

- Patient demographic, medical, diagnostic, and treatment records stored in SAMS
- A list of diagnoses from the diagnosis knowledge base for use with all of the diagnostic algorithms
- Questions, possible answers, and prior and conditional probabilities from the Bayesian knowledge base
- Questions, possible answers, and the branching tree structure from the rules knowledge base
- Questions, possible answers, constants, and weights from the classification functions knowledge base
- Questions, possible answers, layers, nodes, connectivity, and activation functions from the neural network knowledge base
- Therapeutic planning from the treatment plans knowledge base
- Medical information from the medical reference library

- Training scenarios from the medical education knowledge base

3.3 Inputs and Outputs. The CAMD module will provide an expert system shell, essentially an empty framework into which developers of knowledge bases and diagnostic algorithms can add medical information, inference engines, rules, examples, and training scenarios. The general categories of information that can be loaded for each knowledge base are described below along with their associated outputs. Specific contents of each information category and corresponding outputs are defined in the System/Subsystem Specification document for the CAMD module.

3.3.1 Inputs.

a. Bayesian Knowledge Base. The CAMD module knowledge base editor will accept input from developers for the following categories of information:

(1) List of medical diagnoses.
(2) List of signs and symptoms associated with each diagnosis.
(3) List of prompts for the patient's presenting signs and symptoms (questions).

(4) Alternative responses for each prompt (answers).

(5) Prior probabilities for each diagnosis.

(6) Conditional probabilities (weights) for each response alternative for each diagnosis.

b. Expert Rules Knowledge Base. The CAMD module knowledge base editor will accept input from developers for the following categories of information:

(1) List of medical diagnoses.

(2) List of signs and symptoms associated with each diagnosis.

(3) List of prompts for the patient's presenting signs and symptoms (questions).

(4) Alternative responses for each prompt (answers).

(5) The set of rules (e.g., branching tree structure).

c. Classification Functions Knowledge Base. The CAMD module knowledge base editor will accept input from developers of diagnostic algorithms using regression analysis and discriminant analysis methods for the following categories of information:

(1) List of medical diagnoses.

(2) List of signs and symptoms associated with each diagnosis.

(3) List of prompts for the patient's presenting signs and symptoms (questions).

(4) Alternative responses for each prompt (answers).

(5) Prior probabilities (classification function constants).

(6) Classification weights for each response alternative for each diagnosis.

d. Artificial Neural Network Knowledge Base. The CAMD module knowledge base editor will accept input from developers for the following categories of information:

(1) List of medical diagnoses.

(2) List of signs and symptoms associated with each diagnosis.

(3) List of prompts for the patient's presenting signs and symptoms (questions).

(4) Alternative responses for each prompt (answers).

(5) Number of layers in the neural network.

(6) Number of nodes in the neural network associated with each layer.

(7) Pattern of interconnections among the nodes.

(8) Assigned weight for each connection.

(9) Activation function for each node (usually the same for all nodes in a layer).

e. Therapeutic Planning Knowledge Base. The CAMD module knowledge base editor will accept input from developers for the following categories of information:

(1) Treatment descriptions and definitions associated with particular diagnoses.
(2) Drug-to-drug interactions and any counter indications.

f. Medical Reference Library Knowledge Base. The CAMD module knowledge base editor will accept input from developers for the following categories of information:

(1) Medical textbooks.
(2) General medical/surgical journals.
(3) Military medical references such as Manual of Medical Department, General Medical Officer Manual, and Radiation Health Specific.
(4) Navy operational documents such as those pertaining to hazardous materials.

g. Medical Education Knowledge Base. The CAMD module knowledge base editor will accept input from developers for the following categories of information:

(1) Training scenarios for learning how to use the diagnostic support available in the CAMD module.

(2) Training scenarios for learning how to use the treatment planning support available in the CAMD module.

(3) Training scenarios for browsing the electronic medical reference library.

3.3.2 Outputs.

a. Bayesian Method. The following outputs will be produced by application of the Bayesian Method to patient signs and symptoms:

(1) Posterior probability of candidate medical diagnoses in rank order.

(2) In the long term, an explanation of how the candidate medical diagnoses were made.

b. Expert Rule Based Method. The following outputs will be produced by application of the Expert Rule Based Method to patient signs and symptoms:

(1) A medical diagnosis that is the end result of the branching tree rule based structure.

(2) In the long term, an explanation of how the medical diagnosis was rendered.

c. Other Statistical Methods. The following outputs will be produced by application of regression analysis and discriminant analysis classification functions to patient signs and symptoms:

(1) Probability of candidate medical diagnoses in rank order.

(2) In the long term, an explanation of how the candidate medical diagnoses were made.

d. Artificial Neural Network Method. The following outputs will be produced by application of the Artificial Neural Network Method to patient signs and symptoms:

(1) The medical diagnosis generated at the final layer of the neural network.

(2) In the long term, an explanation of how the medical diagnosis was rendered.

e. Therapeutic Planning outputs are the following:

(1) Treatment plans for specific diagnoses.

(2) Medical literature citations from which the therapeutic plan was extracted.

(3) Advice about drug-to-drug interactions and any counter indications.

f. Medical Reference Library outputs are the following:

(1) The results of on-line searches for desired medical information by word, author, subject, or title.

g. Continuing Medical Education outputs are the following:

(1) The results of browsing the electronic medical reference library for desired medical information by word, author, subject, or title.

(2) Delivery of training scenarios for learning how to use the available diagnostic support.

(3) Delivery of training scenarios for learning how to use the available treatment planning support.

3.4 Database Characteristics. The CAMD module shell will provide for the incorporation and manipulation of two databases: (1) a patient database that will use SAMS patient data where available, and (2) knowledge bases that will contain medical

reference information and information about how to manipulate the patient data to arrive at suggested diagnoses with their corresponding treatment plans. The CAMD module software will have a set of Data Directory Utilities to provide a means for developers to create, edit, display, or retrieve the individual data elements and tables of information needed to support the functions of the CAMD module.

In the CAMD module design, a data element can be a numeric value, a character string, a date, a time, a logical value, a free text document, or one of a variety of table configurations. Each data element has a unique Element Identification Code, a Primary Name, and a Data Element Type code such as "C" to indicate a character string. Eight kinds of table configurations will be available such as a "list" or "menu" type of selection table where all selection options (table members) are always displayed as a selection menu. In addition, each directory entry must have a set of control parameter values associated with it that are used to govern data entry or selection processes and other operations involving the data element. A detailed description of each data element type and the data element control parameters is contained in the System/Subsystem Specification document for the CAMD module.

3.5 Failure Contingencies. If the CAMD module fails, it most likely will be caused by SAMS itself failing. In the event of system failure, the following alternative courses of action may be taken.

a. Backup - The entire system will be backed up on a daily basis to a storage medium other than the computer hard disk drive. In the event of a hard crash, the latest backup can be restored to the hard drive. Any data entered since the time of the last backup will have to be re-entered.

b. Fallback - If SAMS fails and the CAMD module is not accessible, the medical practitioner will render a medical diagnosis by the method used before CAMD, consulting available hard-copy medical references or requesting a second opinion from a remote supporting medical officer via radio link.

c. Degraded Modes of Operation - If SAMS goes down in the middle of a CAMD module operation, SAMS operational support personnel may be able to reboot the system and bring it back up normally. Depending on what function the CAMD module was performing at the time, some data may be lost. For example, if the CAMD module was in the middle of calculating a predicted diagnosis or

storing patient medical data, some files may be corrupted or left in an incomplete state. Methods for protecting CAMD module files from corruption and for repairing damaged files are defined in the System/Subsystem Specification document for the CAMD module.

SECTION 4. DESIGN CONSIDERATIONS

In designing the system architecture of the CAMD module, an overriding design consideration is to develop a module for integration into SAMS that can accommodate change and growth. An equally important design goal is to develop a modular architecture to provide maximum flexiblity in implementing, updating, and maintaining the module. Since the knowledge bases in the CAMD module will be separate from the patient database, the knowledge bases can be expanded and updated as improvements in the performance of the diagnostic algorithms are verified and validated. New data files then will be provided for installation in SAMS. Further, the CAMD module software must remain compatible with the SAMS software and operating system in the event that SAMS may change.

4.1 System Description. SAMS Version 7.0 has been implemented in the FoxPro 1.03 programming language and runs under the MS-DOS 3.3+ operating system. The next imminent version of SAMS will upgrade the software from FoxPro 1.03 to FoxPro 2.0. As a result, the CAMD module will be developed in FoxPro 2.0 to be compatible with the upcoming SAMS software environment. The CAMD module will avoid the inclusion of any proprietary software.

Table 1 enumerates the initial implementation components of the CAMD module diagnostic application software and support subsystems. The CAMD module has three basic components: Diagnostic Application Software, User Interface Subsystem, and a Data Directory Subsystem. The Data Directory Subsystem provides core utilities used by the User Interface Subsystem and by application programmers and diagnostic algorithm developers to implement, maintain, and augment the data files within the FoxPro environment. Figure 4 shows the user organizational interfaces to the major components of the CAMD module.

4.1.1 CAMD Diagnostic Application Software. FoxPro software used for the diagnostic application component of the CAMD module will have five major subcomponents: Patient Encounter, Diagnosis and Treatment Recommendation, Report Generator, CAMD Utilities, and File Maintenance. The functions to be performed by each of these constituents are as follows:

Patient Encounter

- Register Patient Enter/Edit
- Routine Encounter Enter/Edit
- SF600 Enter/Edit
- Evacuation Enter/Edit

TABLE 1

INITIAL IMPLEMENTATION COMPONENTS OF THE
CAMD MODULE DIAGNOSTIC APPLICATION
SOFTWARE AND SUPPORT SUBSYSTEMS

CAMD DIAGNOSTIC APPLICATION SOFTWARE	**USER INTERFACE SUBSYSTEM**	**DATA DIRECTORY SUBSYSTEM**
Patient Encounter	Security	Create/Edit Directory Entries Utility
Diagnosis and Treatment Recommendation	Window and Screen Handling Utilities	Display Directory Entries Utility
Report Generator	Menu Management and Graphics Handling	Table Entry/Edit Utilities
CAMD Utilities	Procedure Driver	Retrieve Table Entries Utilities
File Maintenance	Help Interface	Data Element Entry and Selection Utilities
	Database Editors	
	Knowledge Base Editor	
	Medical Reference Library	
	Training Scenarios	
	SF600 Form Generator	
	SAMS Interface	

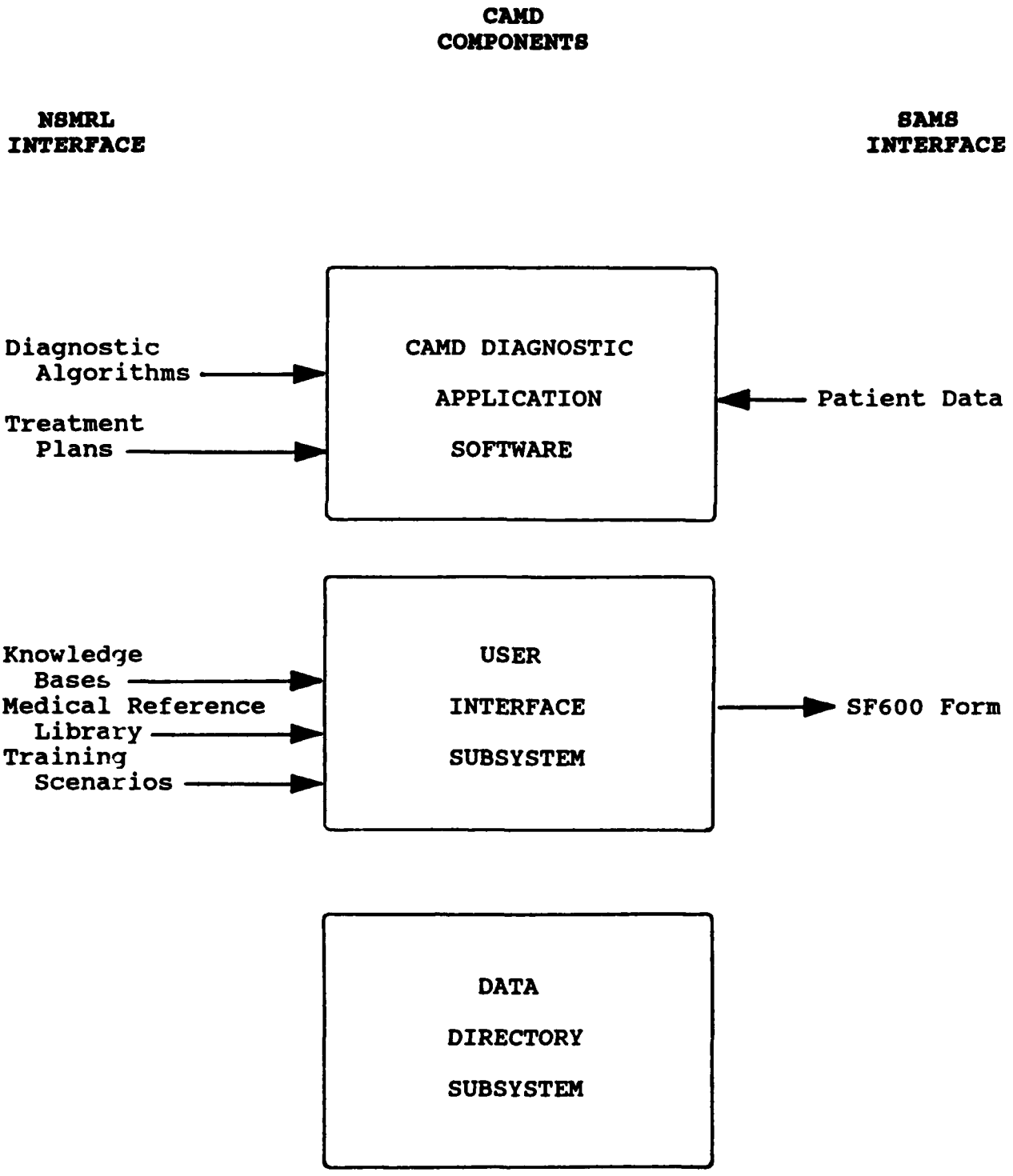


Figure 4. User Organizational Interfaces to the Major Components of the CAMD Module.

Diagnosis and Treatment Recommendation

- Enter Selected Complaint(s)
- History and Physical Enter/Edit
  - (Signs and Symptoms)
- Enter Provider Diagnosis
- Provide Diagnostic Assistance
- Provide Treatment Recommendation

Report Generator

- Ad Hoc Displays (Browse)
- Print SF600

CAMD Utilities

- User ID
- Log-on Security
- CAMD Facility File and Setup
- Archive Patient Records

File Maintenance

- Add/Edit ICD-9-CM File
- Add/Edit Diagnostic Method

In the initial implementation of the CAMD diagnostic application software, Bayesian algorithms will be used to provide a diagnostic recommendation for two sets of signs and symptoms---abdominal pain and chest pain. In the future, three additional

areas of diagnostic assistance will be included---ocular, dental, and trauma. Rule-based algorithms for generating a differential diagnosis will be added to the next iteration of the CAMD diagnostic application software.

4.1.2 User Interface Subsystem. Eleven major elements will comprise the User Interface Subsystem: Security, Window and Screen Handling Utilities, Menu Management and Graphics Handling, Procedure Driver, Help Interface, Database Editors, Knowledge Base Editor, Medical Reference Library, Training Scenarios, SF600 Form Generator, and a SAMS Interface. Security will be provided for database files and user's IDs. Window and screen handling utilities will allow the application programmer and diagnostic algorithm developer to use pop up windows or scrolling and to choose the foreground and background color of the screen. The application programmer and diagnostic algorithm developer will also have the capability to manage menus and employ graphics. The procedure driver will further provide the capability to create menus and determine the method of prompting for inputs from the end-user. The help interface will allow the application programmer and diagnostic algorithm developer to author help text for each prompt in the CAMD diagnostic application.

Database editors will facilitate the maintenance and updating of diagnostic application files and tables. The

knowledge base editor will allow knowledge data to be entered, edited, and retrieved without the author being required to know the file structure.

A medical reference library can be constructed with this subsystem and accessed using a search engine. Training scenarios can be created and can be driven by the diagnostic engines. The SF600 form will be generated by this subsystem, to be filled in as a SOAP memo by the CAMD diagnostic application software for each patient diagnostic encounter. Finally, this subsystem will provide the interface to SAMS, passing the SF600 SOAP memo to SAMS to use where appropriate. The SAMS database will be read-only to the CAMD module.

4.1.3 Data Directory Subsystem. The Data Directory Subsystem has five kinds of utilities: Create/Edit Directory Entries Utility, Display Directory Data Entries Utility, Table Entry/Edit Utilities, Retrieve Table Entries Utilities, and Data Element Entry and Selection Utilities. Data directory utilities software provides a means for creating all individual data elements and tables of information necessary to support an operational application-specific module such as CAMD. This software will provide identification, definition, and editing utilities for creation of a variety of data elements and associated parameter information necessary to control normal use within an application

program or subsystem utility. The software also provides utilities to display directory entries according to several selection methods; to input, edit, and display or print entries in several types of tables; and to execute either data element entry or selection (retrieval) actions.

4.2 System Functions. The six major functions of the CAMD module are expanded below:

a. Diagnostic Support Function: Provide medical diagnostic assistance. This function will allow the medical practitioner to request assistance in making a medical diagnosis while entering a diagnostic encounter record or to simply enter the patient's signs and symptoms along with his own diagnosis. This function will extract patient data from SAMS to formulate the diagnostic encounter. The medical practitioner's diagnosis will be requested before presenting diagnostic assistance. When diagnostic assistance is provided, it will indicate how a diagnosis was made. A record will be kept of the inputs (key strokes) and outputs to serve as an audit trail for later analysis.

Artificial Neural Network algorithms will be implemented as static systems. That is, the learning

feature used during the development of the neural network will be turned off before the algorithm is installed in SAMS. Otherwise, the manner in which a diagnosis is arrived at could be different at various sites or ships for the same set of signs and symptoms.

b. Therapeutic Plan Function: This function will facilitate proper management of the patient after a medical diagnosis is made. Specific requirements include the ability to call up medical references from which the treatment plan was extracted, the capability of looking up information by disease or treatment plans, and the ability to tailor treatment plans by ship type to take into account available resources and the location and mission of the ship.

c. Medical Reference Library Function: Provide a comprehensive source of medical reference data. The initial implementation of this function will include simple drop down menus, a help facility, graphics, and sound capabilities. The search engine will allow searching or browsing by word, author, subject, or title using simple Boolean search expressions (i.e., AND, OR, NOT). The initial implementation of this function will be able to search only one document at a time. Anticipated improvements will expand the search

capability to multiple documents per search, incorporate a Graphical User Interface, mouse support, and modifications to simple Boolean searching logic to allow for more complex search expressions.

d. Diagnostic Encounter Record Function: Create a computer-stored, patient diagnostic encounter record. The diagnostic encounter record, at a minimum, will consist of a demographic component containing patient information; an event component with date/time stamped information collected by the medical practitioner and the circumstances surrounding the patient encounter; and a result component containing medical findings, diagnosis, and disposition. The diagnostic encounter record will be passed to SAMS in the SOAP format. All surface behavior of the CAMD module should be the same as SAMS to the extent that it is functional.

e. Continuing Medical Education Function: Provide an on-site, computer based tutoring capability. It will be possible to develop training scenarios to learn how to use the diagnostic and therapeutic planning support available in the CAMD module. The diagnostic engines that perform the calculations or interpretations of various diagnostic algorithms can also be used to drive training in the use of diagnostic assistance. Training

scenarios will consist of typical cases in which the trainee will be provided with hypothetical patient demographic data and medical history information along with the patient's presenting signs and symptoms. The trainee will respond to the prompts in the diagnostic algorithm and be supplied with a recommended diagnosis. The trainee will be instructed in how a diagnosis was made. The training scenario will also provide the correct diagnostic outcome for comparison with the diagnosis or diagnoses actually provided so that the trainee can elect to work through the case again to improve his understanding of the process.

Training in how to browse the electronic medical reference library will include explanations of simple Boolean search expressions such as AND, OR, NOT; how to conduct "wild card" searches for common roots; and proximity searches for two words within a specified distance from each other. Instruction will also be provided in how to edit a search. This function should accommodate several levels of training to match the expertise of the trainee.

f. Knowledge Base Authoring Function: Create and edit resident knowledge bases. The User Interface Subsystem of the CAMD module will include a knowledge base editor

to support this function. A knowledge base inference engine will calculate or interpret various diagnostic algorithms. The knowledge base editor will make it possible to add knowledge bases for additional diseases, to modify the information in an existing knowledge base, and to delete an out-of-date knowledge base. The knowledge base editor must include a defined architecture for each of the diagnostic methods encompassing the following:

(1) Questions and answers about patient signs and symptoms, and the prior and conditional probabilities for the Bayesian Method.

(2) Questions and answers about patient signs and symptoms, and the branching tree structure for the Expert Rule Based Method.

(3) Questions and answers about patient signs and symptoms, classification function constants, and classification weights for regression analysis and discriminant analysis (Other Statistical Methods).

(4) Questions and answers about patient signs and symptoms, number of layers, number of nodes in each layer, interconnections of nodes, and activation functions for the Artificial Neural Network Method.

To further support the Knowledge Base Authoring Function, BatchNet, a neural network program, will be used to load variable weights for each connection in an Artificial Neural Network. ExSys, a rule-based Artificial Intelligence program, will be used to load textual rules for the Expert Rule Based Method and convert them for use by the knowledge base editor.

A set of CAMD system utilities will provide for security and maintenance of the CAMD files. Security procedures will provide physical security of the patient medical data files and user password protection against illegal access to the CAMD module. The Data Directory Subsystem will provide for creation and maintenance of all data elements and table configurations, along with associated control parameters. Additional CAMD utilities will allow the system manager to back up, archive, purge, and re-index CAMD files as well as check for database integrity. Other maintenance functions will facilitate managing menus and graphics, window and screen handling, and the help interface.

Finally, a System Version Editor (SVE) will document all changes made to the CAMD module since the latest version was installed in SAMS. This function will support the design goal of developing a module to accommodate change and growth.

4.3 Flexibility. The CAMD module will use flexible software and hardware design and architecture to accommodate changing system requirements and to permit interface with other systems. Advanced system design and software engineering technology will be used to provide:

a. A flexible module that can respond to evolving functional requirements.

b. Maximum software reusability and portability.

c. A module that accommodates evolving technology and conceptual changes.

The module uses the concept of modular expansion to accommodate changes in government regulations and advances in technical developments. Modular expansion means that the module makes use of interim change packages so that total module redesign or replacement is not necessary. The module incorporates a design with application software that is portable to multiple operational platforms. This design also allows capabilities to be extended.

The CAMD module will include a System Version Editor (SVE) that will allow changes, additions, and deletions to the files. This editor will create a version change record that will

document all of the changes made by the update. The record will contain the name of the person updating the module, the files edited, and each edit made, line by line, including the original line of code and the changed version line. A printed copy of each of the version updates will be kept by the institution responsible for the updating of the CAMD module. The CAMD module program documentation will be updated to reflect editing whenever new versions of the module are issued or as need warrants.

The SVE will have the ability to incorporate new files including new diagnosis, treatment, or disease information. When new files are added, the names of the people and the institution responsible for developing these new files will be recorded, along with all reports and publications documenting the new files. The new file changes will be incorporated into all program documentation including the user, operator, and programmer guides.

4.4 System Data. When the CAMD module is used for diagnostic support, the module will keep a record of the inputs (key strokes) and outputs of that interaction. This record will include all questions asked of the patient (prompts), all answers to the questions (responses), and the suggested diagnoses provided by the CAMD module. Once a differential diagnosis has been made by the medical practitioner, for legal reasons the CAMD

module will not allow the medical practitioner to remove the signs and symptoms data on which the diagnosis was based.

The audit trail provided by this record will be removed from the CAMD module after each deployment for later analysis. The uses for this audit trail are the following:

a. Provide medical encounter information for quality assurance purposes.

b. Investigate failures of the diagnostic algorithms with the goal of remedying the cause of the failure and improving future performance.

c. Gather additional case data to enhance existing diagnostic algorithms.

The questions asked of the patient (prompts) and the possible answers to the questions (responses) used by the Bayesian diagnostic algorithm for chest pain are defined in Appendix A, Example of Questions and Possible Answers Used by the Bayesian Method To Suggest Diagnoses for Chest Pain.

SECTION 5. ENVIRONMENT

5.1 Equipment Environment. The initial version of the CAMD module will operate in the existing SAMS hardware environment. The current SAMS hardware consists of the following:

a. Zenith microcomputer (Z-248) with 512 kilobytes of RAM (640 kilobytes of RAM are recommended).

b. Monochrome or color (CGA through VGA) monitor.

c. Two 20 megabyte hard disk drives (with limited free space).

d. MS-DOS 3.3+ operating system.

The module can operate on a local area network or on the network used on larger ships such as aircraft carriers.

Future versions of the CAMD module must support compact disk read-only memory (CDROM) medical libraries and will require the following minimal hardware configuration:

a. 80386 microcomputer (33 MHz) with 640 kilobytes of RAM (upgradable to 4 megabytes of RAM).

b. 5-1/4" and 3-1/2" disk drives (1.2 and 1.44 megabytes).

c. 80 megabyte hard disk drive.

d. 80 megabyte tape backup.

e. VGA or 8514 Color Monitor with 1024 x 768 resolution and 256 colors.

f. Video 5" CDROM.

g. Mouse.

h. Laser printer (at least 4 pages per minute).

i. MS-DOS 4.0 or above operating system with Windows.

5.2 Support Software Environment. All CAMD module top level programs should be callable from the SAMS FoxPro 2.0 top level menu and should have the look and feel of SAMS Version 7.0. The operating system will be MS-DOS 3.3+. The CAMD module must use appropriately formatted, existing SAMS patient data. Existing SAMS patient data include demographic information (name, rank, gender, and age), past to current medical history, vital signs, examination findings, and laboratory results. Free-form textual

data will not be used for diagnostic decision making because the CAMD module will not have an extensive natural language processor to interpret text.

The CAMD module will undergo user testing at the Naval Health Research Center (NHRC), San Diego, California prior to integration into SAMS. The actual testing will consist of performing 20 tasks designed to fully exercise the CAMD module and verify the ability of this module to be integrated into the SAMS system. The following areas of component and integration testing will be conducted:

- Verifying data links within the CAMD module
- Verifying data links between the CAMD module and the SAMS system
- Entering test sets of actual patient case data into each disease area in the CAMD module
- Generating probable diagnoses for each disease area that accurately reflect the correct diagnosis by expert medical opinion
- Editing and updating patient diagnostic encounters
- Generating the SF600 form in a SOAP format and passing it to the SAMS system

NHRC will be responsible for providing the equipment, facilities, and in-house operators to conduct testing of the CAMD

module. After problems and deficiencies revealed by the testing have been resolved or corrected, the CAMD module will be judged acceptable and ready for field testing.

5.3 Communications Requirements. Communication requirements for the CAMD module itself are minimal. The module will be able to operate on a local area network or on the network used on larger ships such as aircraft carriers. Additional communications requirements are commercially available communications software packages such as ProComm Plus 2.0. No modem is required for the initial implementation of the CAMD module. As the communications requirements for the SAMS system may increase, the CAMD module will be able to take advantage of any expanded communications capability of the SAMS system environment.

5.3.1 Graphic Overview of the Communications Requirements. The CAMD module will be integrated into the SAMS system, and as a consequence, the module will operate within the communications capabilities of the SAMS system environment. Currently, these capabilities are the following:

- Local Area Network
- ProComm Plus 2.0

5.3.2 Hardware. The communications hardware required to support the CAMD module will be what exists in the SAMS system hardware configuration. No new hardware acquisition will be dictated by any requirements of the CAMD module. However, as the SAMS hardware platform may be upgraded, the CAMD module will be able to take advantage of the enhanced capability of newer hardware technology.

5.3.3 Software. The communications software required to support the CAMD module will be what exists in the SAMS system. No special requirements for communications software will emanate from the CAMD module. However, if the communications capability of the SAMS system environment is enhanced, the CAMD module will also be able to take advantage of this increased capability.

5.4 Interfaces. The CAMD module will be integrated into the SAMS system rather than functioning as a stand-alone module. The module in its initial implementation will not interface to any other applications system or subsystem. However, as interfaces between SAMS and other medical information systems may be developed, the CAMD module will also be provided with the capability to interface and exchange patient data between these systems. Existing medical information systems that are candidates for accomplishing such an interface are ACQESS, CHCS,

and RAPS. Other medical information systems may become additional candidates in the future.

5.5 Summary of ADP Impacts. There will be minimal, if any, ADP organizational impacts or operational impacts associated with the introduction of the CAMD module. However, ADP development impacts on personnel and resources associated with the CAMD module will affect NSMRL, PHS OMIL, and NHRC.

5.5.1 ADP Organizational Impacts. ADP organizational impacts, if any, will be minimal. Since the CAMD module will be integrated into the SAMS system, it will not require any modifications to or elimination of existing positional responsibilities; nor will it require the addition of any new responsibilities for the CAMD module itself. Periodic updates of the CAMD module on the SAMS system will be accomplished by following instructions for installing a floppy diskette that will overwrite existing files.

5.5.2 ADP Operational Impacts. No ADP operational impacts are anticipated by integration of the CAMD module into the SAMS system.

5.5.3 ADP Development Impacts. Development of the CAMD module will impact on personnel and resources at NSMRL, PHS OMIL, and NHRC. NSMRL will be tasked with developing and evaluating the diagnostic algorithms for chest pain, abdominal pain, ocular problems, dental problems, trauma and possibly gynecologic and psychiatric disorders. NSMRL will also be responsible for developing the electronic medical reference library.

PHS OMIL will be responsible for large scale data collection of chest pain, abdominal pain, and eye disease clinical cases and verification and validation of the clinical data in these cases.

NHRC will develop the CAMD shell into which the best performing diagnostic algorithms, medical reference material, and treatment information can be loaded. NHRC will also provide the equipment, facilities, and in-house operators to conduct user testing of the CAMD module. As overseer of the CAMD program, NHRC will coordinate the various CAMD research efforts so that the CAMD module can be readily moved from an R&DTE environment to SAMS.

5.6 Failure Contingencies. If the CAMD module fails, it most likely will be caused by SAMS itself failing. In the event of a system failure, the alternative courses of action that may be taken to satisfy the information requirements are restoring the

latest backup of the SAMS system; rendering a medical diagnosis by the method used before CAMD; and functioning temporarily with degraded modes of operation. Failure contingencies for the CAMD module are discussed in more detail in paragraph 3.5.

5.7 Assumptions and Constraints. The assumptions and constraints listed below pertain to the current SAMS software and hardware environment. If SAMS changes, the assumptions and constraints will also change.

5.7.1 Assumptions.

a. The CAMD module will be initialized on the SAMS system using floppy diskettes.

b. Resources will be available for CAMD module development, enhancement, maintenance, acquisition, and deployment.

c. The CAMD module will be expanded and improved as ADP technology develops and new capabilities and resources become available.

d. Periodic updates of the CAMD module on the SAMS system will be accomplished by installing a floppy diskette.

5.7.2 Constraints.

a. The CAMD module software must be compatible with SAMS Version 7.0 software and the MS-DOS 3.3+ operating system.

b. The CAMD module software must operate on the same hardware as SAMS.

c. Integration of the CAMD module into SAMS should require a minimum of new software or hardware purchases.

d. Data files must comply with Privacy Act requirements, medical records confidentiality, and security considerations.

e. The CAMD module must avoid duplication of data files.

SECTION 6. SECURITY

6.1 Background Information. The CAMD module as well as the SAMS system itself do not contain any classified information that would require security protection. However, they do contain patient medical encounter data, the privacy of which must be protected. Consequently, the Federal Privacy Act of 1974 applies. ADP security procedures for the medical database files and user identification will be in accordance with SECNAVINST 5239.2. Privacy Act security will conform to the Federal Information Processing Standards Publication 41, Computer Security Guidelines for Implementing the Privacy Act of 1974, 30 May 1975.

6.2 Control Points, Vulnerabilities, and Safeguards. Control points for maintaining the privacy of patient medical encounter data are at the interface between the CAMD module and the SAMS system, and access to CAMD medical database files. Vulnerabilities are unauthorized access to patient demographic, medical, diagnostic, and treatment data; and to the diagnostic and therapeutic knowledge bases in the CAMD module. Safeguards will be security software for medical database files and user identification, and compiled versions of the knowledge bases.

6.2.1 Control Points. The control points in the CAMD module where privacy of medical database files must be protected are the following:

a. Transfer of patient demographic and medical history data from the SAMS system to the CAMD module.

b. Access to the patient demographic, medical, diagnostic, and treatment data files within the CAMD module.

c. Access to the diagnostic and therapeutic knowledge bases within the CAMD module.

d. Transfer of patient diagnostic encounter data from the CAMD module to the SAMS system.

6.2.2 Vulnerabilities. Vulnerabilities at each of the control points are the following:

a. Unauthorized access to patient demographic and medical history data transferred to the CAMD module from SAMS.

b. Unauthorized access to the patient demographic, medical, diagnostic, and treatment data files within the CAMD module.

c. Tampering with the diagnostic knowledge bases within the CAMD module that determine how diagnoses are made.

d. Tampering with the therapeutic knowledge base within the CAMD module that provides treatment plans appropriate to diagnoses.

e. Unauthorized access to the patient diagnostic encounter record as it is transferred from the CAMD module to the SAMS system.

6.2.3 Safeguards. The CAMD module will incorporate the following safeguards to protect the privacy of the medical database files:

a. The Security software of the CAMD User Interface Subsystem will provide security for both medical database files and user identification. Users of the CAMD module will be required to enter passwords to gain access to the module. The database files, when they are initially created, will be assigned an attribute making it possible to lock out users.

b. Users of the CAMD module will be notified by on-screen reminders that the files created by the module contain

the patient's name, social security number, and any other identifying data elements as well as medical information that is subject to the Privacy Act of 1974.

c. The knowledge bases in the CAMD module will be compiled, making it impossible for users to tamper with them. The only way that they can be changed is by completely replacing an existing knowledge base with an updated, compiled version.

6.3 System Monitoring and Auditing. The patient medical database will be a compilation of diagnostic encounter records generated within the CAMD module and then appended to the historical medical encounter record in the SAMS system. As a consequence, ultimate protection of the privacy of the historical patient medical record, which resides in data files in SAMS and is read-only to the CAMD module, will be the responsibility of the SAMS system itself. All system monitoring will be conducted under the auspices of SAMS operations.

The CAMD module will keep an audit trail of the questions asked of all patients (prompts), all answers to the questions (responses), and the suggested diagnoses. After each deployment, this audit trail will be removed from the CAMD module for analysis by the CAMD module developers to facilitate quality

assurance, to improve the accuracy of medical diagnostic support, and to gather additional case data for enhancing the existing diagnostic algorithms. During the time that the audit trail resides in the CAMD module, the privacy of this data file will be protected by locking out users of the module.

SECTION 7. SYSTEM DEVELOPMENT PLAN

The CAMD module will be developed in parallel with SAMS operations. The SAMS system will continue operations at all of the sites where it is deployed and will not be delayed in its own ongoing enhancement by the CAMD module not being immediately available. As CAMD features are implemented, tested, and accepted for integration into SAMS, they will be added to the SAMS system with no programming required to install them. The CAMD module will be initialized on the SAMS system using floppy diskettes; periodic updates of the CAMD module will be accomplished by installing a floppy diskette that will overwrite existing files and/or create new files.

7.1 CAMD Module Documentation. The documentation for the CAMD module will include the following:

- Functional Description
- System/Subsystem Specification
- Software Test Plan:
  - Component Test Plan
  - Integration Test Plan
  - Field Test Plan
- User Manual
- Operations Guide

- Instructions for Installing Diskettes into SAMS

7.2 Initial Development. Initial work will concentrate on the following tasks:

a. Develop a shell in FoxPro Version 2.0 that will allow for the rapid incorporation of diagnostic algorithms and therapeutic plans for new and existing diseases.

b. Review current database structures for SAMS Version 7.0 compatibility.

c. Design and program the knowledge base editor.

d. Complete preliminary CAMD User Interface Subsystem.

e. Test the Bayesian algorithm used in suggesting medical diagnoses based on presenting signs and symptoms for chest pain and abdominal pain.

f. Add treatment recommendations for each new disease.

g. Implement a rudimentary Medical Reference Library capability.

7.3 Continuing Development. Follow-on work will focus on the following enhancements:

a. Complete final CAMD User Interface Subsystem.

b. Test the Expert Rule Base algorithm used in suggesting a differential diagnosis based on presenting signs and symptoms for ocular problems, dental problems, and trauma. Other problem areas under consideration for medical diagnostic support are gyncologic and psychiatric disorders.

c. Implement an advanced Medical Reference Library capability.

d. Develop a medical education knowledge base.

7.4 Participating Organizations.

a. NSMRL will develop and evaluate diagnostic algorithms and the electronic medical reference library.

b. PHS OMIL will be responsible for large scale collection of clinical case data, and verification and validation of the clinical data.

c. NHRC will develop the CAMD shell and provide the necessary resources to conduct user testing. As overseer of the CAMD module development, NHRC will coordinate the various CAMD research efforts so that the CAMD module can be readily moved from an R&DTE environment to SAMS.

7.5 A Look to the Future. The CAMD module must be able to accommodate change. Any design decisions must allow, to the maximum extent possible, the addition of new diagnostic algorithms, disease areas, graphics techniques, and communications capabilities. The module should be capable, in its final form, of communicating with the IEEE standard medical data bus.

An advanced Medical Reference Library will require a sophisticated search engine and CDROM storage of the library. Interactive video systems as training devices, such as the Computer Assisted Medical Interactive-Video System (CAMIS), offer powerful instructional capability if they can be integrated into the CAMD module. The limiting factor is the SAMS hardware configuration.

Future requirements of the CAMD module might be the ability to accept input from a variety of electronic devices (e.g., EKG

machines, optical scanners, voice activated inputs, bar code readers, and touch screens). Exchange of patient data between CAMD/SAMS and other medical information systems such as ACQESS, CHCS, and RAPS is also a possibility and will depend on the communications capability of the SAMS system.

SECTION 8. COST FACTORS

8.1 R&DTE Cost Factors. The cost factors associated with developing, testing, and evaluating the CAMD module are the following:

a. Developing diagnostic algorithms.

b. Obtaining clinical case data to validate the diagnostic algorithms (the largest cost).

c. Verifying the completeness and accuracy of the clinical case data.

d. Developing the contents of the knowledge bases.

e. Loading medical reference sources into the search engine.

f. Designing and developing the CAMD module software in FoxPro Version 2.0.

8.2 Implementation Cost Factors. No additional costs should be incurred by the SAMS system in order to integrate the CAMD module into the SAMS environment. All that should be required is the

distribution of magnetic media to initialize the CAMD module and keep it updated with current knowledge. However, if the SAMS hardware platform is upgraded, the cost factors may change. Two notable areas where costs could be incurred to invest the SAMS system with greater capability resulting from the introduction of new technology are CDROM and interactive video. These technologies would make available to the medical practitioner a large but compact library of medical information in a variety of formats such as textual and graphic including diagrams, drawings, and photographs.

8.3 Benefits. The major benefits anticipated from integrating the CAMD module into the SAMS system are the following:

a. A better determination of when to evacuate a patient.

b. Knowing at an early stage if additional medical resources beyond what the ship has available are needed.

c. Keeping the medical practitioner's knowledge and skills updated through electronic access to current medical references and training materials.

APPENDIX A. EXAMPLE OF QUESTIONS AND POSSIBLE ANSWERS USED BY THE BAYESIAN METHOD TO SUGGEST DIAGNOSES FOR CHEST PAIN

Questions about Patient	Allowable Responses to Questions
PATIENT CHARACTERISTICS	
Mood	0 = Normal, 1 = Anxious, 2 = Distressed, 3 = In Shock
Color	0 = Normal, 1 = Pale, 2 = Flushed, 3 = Cyanotic, 4 = Jaundiced (Check Palms, Conjunctiva)
Height	In nn.n inches
Weight	In nnn pounds (lbs.)
Build	0 = Thin, 1 = Average, 2 = Heavy, 3 = Obese
Smoking History	0 = Nonsmoker, 1 = Light Smoker (<1 pack/day), 2 = Moderate (1-2 packs/day), 3 = Heavy (>2 packs/day)
Smoker Status	0 = Nonsmoker, 1 = Smoker (automatically computed from Smoking History)

Questions about Patient	Allowable Responses to Questions
VITAL SIGNS	
Age	In nn (computed from Visit Date minus Date of Birth)
Temperature	In nnn.n degrees Fahrenheit
Pulse	In nnn beats per minute
Respiration	In nn respirations per minute
Systolic Blood Pressure	In nnn (mm. Hg.)
Diastolic Blood Pressure	In nnn (mm. Hg.)
CHEST PAIN DESCRIPTION	
Duration of Pain	In nn hours
Duration of Pain Ranges	0 = <1 hour, 1 = 1-2 hours, 3 = 2-4 hours, 4 = 4-12 hours, 5 = >12 hours
Onset of Pain	1 = Gradual, 2 = Sudden
Course of Pain	1 = Continuous, 2 = Intermittent
Site of Pain	1 = Substernal, 2 = Across, 3 = Left Side, 4 = Right Side, 5 = Epigastric, 6 = Other

Questions about Patient	Allowable Responses to Questions
CHEST PAIN DESCRIPTION (CONTINUED)	
Radiation of Pain	1 = Left Arm, 2 = Right Arm, 3 = Both Arms, 4 = Back, 5 = Shoulder, 6 = Neck, 7 = Jaw, 8 = Other, 0 = Does Not Radiate
Numbness (with/after Pain)	0 = No, 1 = Yes
Severity of Pain	0 = Moderate, 1 = Severe
Progress of Pain	0 = Better, 1 = No Change, 2 = Worse
Aggravating Factors	1 = Movement, 2 = Sitting, 3 = Cough, 4 = Breathing, 5 = Other, 0 = No Aggravation
Relieving Factors	1 = Nitro, 2 = Rest, 3 = Walking, 4 = Other, 5 = None
Type of Pain (Description)	1 = Tight, 2 = Sharp, 3 = Gripping, 4 = Burning, 5 = Dull, 6 = Stabbing, 7 = Nagging, 8 = Aching, 9 = Heavy, 10 = Crushing, 11 = Pressing

Questions about Patient	Allowable Responses to Questions
OTHER CHEST PAIN SYMPTOMS	
Shortness of Breath (Dyspnea)	0 = No, 1 = This Illness, 2 = Habitual
Paroxysmal Nocturnal Dyspnea	0 = Absent, 1 = Present
Cough	0 = No, 1 = This Illness, 2 = Chronic
Nausea	0 = No, 1 = Yes
Vomiting	0 = No, 1 = Yes
Appetite	0 = Normal, 1 = Increased, 2 = Decreased
Bowels	0 = Normal, 1 = Constipated, 2 = Diarrhea
Sputum	0 = Absent, 1 = Present
Orthopnea	0 = Absent, 1 = Present
Esophageal Reflux Symptoms	0 = Absent, 1 = Present

Questions about Patient	Allowable Responses to Questions
PATIENT HISTORY	
Previous Chest Pain	0 = No, 1 = Yes
Previous Cardio-Pulmonary	0 = No, 1 = Yes
Previous History of	1 = Myocardial Infarction,
	2 = Angina, 3 = Bronchitis,
	4 = Hypertension, 5 = Diabetes,
	0 = No History of These Diseases
Previous Major Surgery	0 = No, 1 = Yes
Smoker	0 = No, 1 = Yes
PHYSICAL EXAMINATION	
Sweating	0 = No, 1 = Yes
Shivering	0 = No, 1 = Yes
Cold or Clammy	0 = No, 1 = Yes
Jugular Venous Pulse	0 = Normal, 1 = Raised
Respiratory Movement	0 = Normal, 1 = Abnormal
Heart Sounds	0 = Normal, 1 = Abnormal,
	2 = PVC's (Enter _____)
	3 = S3/S4 (Enter _____
Percussion	0 = Normal, 1 = Dull,
	2 = Hyper-Resonant

Questions about Patient	Allowable Responses to Questions
PHYSICAL EXAMINATION (CONTINUED)	
Chest Sounds	0 = Normal, 1 = Rhonchi, 2 = Rales, 3 = Decreased
Edema (Swelling)	0 = Absent (None), 1 = Ankles, 2 = Other
Calf Tenderness	0 = No, 1 = Yes
Chest Wall Tenderness	0 = No, 1 = Yes
LABORATORY/ECG RESULTS	
SGOT	In nnn (IU/L)
SGOT Ranges	1 = <25, 2 = 25-50, 3 = 51-100, 4 = 101-200, 5 = >200
ECG Results	1 = ST Elevation, 2 = ST Depression, 3 = T Depression, 4 = Q Waves, 5 = Arrythmia, 0 = Within Normal Limits

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATE COVERED
	October 1992	Interim - FY92

4. TITLE AND SUBTITLE Naval Shipboard Non-Tactical ADP Program (SNAP) Automated Medical System (SAMS) Computer Assisted Medical Diagnosis (CAMD) Module Functional Description

5. FUNDING NUMBERS
Program Element: 63706N
Work Unit Number:
0095.005-6103

6. AUTHOR(S)
Thomas R. Bonifield, Ph.D. and James D. Felson, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Health Research Center
P. O. Box 85122
San Diego, CA 92186-5122

8. PERFORMING ORGANIZATION
Report No. 92-23

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Naval Medical Research and Development Command
National Naval Medical Center
Building 1, Tower 2
Bethesda, MD 20889-5606

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution is unlimited.

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

Medical care aboard U.S. submarines and small surface ships is rendered by specifically trained Independent Duty Corpsmen. To provide these corpsmen with important diagnostic and treatment informaton while deployed, a Computer Assisted Medical Diagnosis (CAMD) module has been conceived. The Functional Description for the CAMD module was developed to define the CAMD module's capability in terms of functions designed to meet the needs of Independent Duty Corpsmen. The major functions identified include: Diagnostic Support, Theraputic Plan Development, Medical Reference Library, Maintain a Diagnostic Record, Medical Education, and Knowledge Base Authoring.

14. SUBJECT TERMS

Computer Assisted Diagnosis	Medical Diagnosis
Knowledge Base	Bayesian Method
Expert System	Rule-Based System

15. NUMBER OF PAGES 112

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited